DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: ~~1/22/02~~ 12/03/02

From: Gloria Chang, IDS/Pharmacist, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-820

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Dietary Ingredient: Agaricus blazei Murill

Firm: Iwade Research Institue of Mycology Company, Ltd.

Date Received by FDA: 01/24/02

90-Day Date: NA

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached correspondence for the aforementioned dietary ingredient should be placed on public display in docket number 95S-0316 as soon possible. The 90-day date is not applicable.. Thank you for your assistance.

Gloria Chang

Gloria Chang, IDS/Pharmacist

Attachments

95S-0316

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

APR 5 2002

Toshimitsu Sumiya
President
Iwade Research Institute of Mycology Company, Ltd.
1-9, Suehiro-cho
Tsu, Mie 514-0012 Japan

Re: Docket No. 95S-0316
Report 49 and 76

Dear Mr. Sumiya:

This letter is in response to your letter on behalf of Iwade Research Institute of Mycology Co., Ltd. (Iwade) to the Food and Drug Administration (FDA) about the use of the dried mushroom or extract of *Agaricus blazei* Murrill as a dietary ingredient. Your letter dated January 15, 2002 was received and filed by FDA on January 24, 2002. In your letter, you indicate that you want to withdraw your new dietary ingredient notification on an extract of *Agaricus blazei* Murrill. Your letter also states that Iwade intends to market the dried mushroom of *Agaricus blazei* Murrill instead of an extract, because you have determined that the dried mushroom was marketed prior to October 15, 1994.

Under 21 U.S.C. 350b(c), a dietary ingredient that was not marketed in the United States as a food or a dietary supplement before October 15, 1994 would be considered to be a "new dietary ingredient." The law at 21 U.S.C. 350b(a)(1) requires that only dietary ingredients which have been present in the food supply as an article used for food in a form that has not been chemically altered can be marketed in dietary supplements without first submitting a new dietary ingredient notification to FDA for review. Please be advised that other commercial uses of a substance (e.g., for topical application, for non-dietary supplement purposes like cosmetics, or for animal use) would not exempt that substance from the new dietary ingredient premarket notification requirement. If the above criteria are not met, 21 U.S.C.350b(2) requires manufacturers or distributors to send FDA a premarket notification on the new dietary ingredient they intend to market as a dietary supplement. This notification must be submitted to FDA at least 75 days prior to the introducing or delivery for introduction of the new dietary ingredient into interstate commerce. The notification must provide history of use and other evidence of safety establishing that the new dietary ingredient is reasonably expected to be safe when used under the conditions of use recommended or suggested in the product's labeling.

FDA is not aware of any evidence that would support your determination that the dried mushroom of *Agaricus blazei* Murrill was marketed as a food prior to October 15, 1994, as a dietary supplement. Before you pursue the marketing of the dried mushroom of *Agaricus blazei* Murrill as a dietary supplement, you will need to provide sufficient documentation to FDA that verifies that this genus and species of dried mushroom was marketed either: 1) as a food and is the same substance you intend to market and is not a chemically altered form of it or 2) as a dietary supplement prior to October 15, 1994.

On May 24, 1999 and August 5, 2000, respectively, FDA received from Iwade an initial and resubmission of a new dietary ingredient premarket notification for this extract. Copies of these notifications are posted with FDA's Docket Management Branch under docket number 95S-0316 as Rpt 49 and 76, respectively. FDA sent correspondence replying to both notifications stating that the evidence provided in the notifications was inadequate to determine that an extract of *Agaricus blazei* Murill in a dietary supplement was reasonably expected to be safe when used as recommended in the product's labeling. Therefore, FDA's letters informed Iwade that a dietary supplement containing the extract of *Agaricus blazei* Murill may be adulterated and marketing it would be a prohibited act under 21 U.S.C. 342(f)(1)(B).

The law at 21 U.S.C 350b(a) requires that FDA place copies of all premarket new dietary ingredient notifications we receive on public display, with the exception of any trade secret or other confidential commercial information they may contain, sometime after 90 days following the respective notifications' filing dates. Therefore, in response to your request to withdraw your new dietary ingredient notification on an extract of *Agaricus blazei* Murrill, we cannot physically remove from the docket the premarket notifications on *Agaricus blazei* Murill extract you sent us in 1999 and 2000. In addition, your January 15, 2002 letter to FDA and this response will be filed in docket number 95S-0316 to supplement the record on your earlier notifications.

Please contact us if you have any questions concerning this matter.

Sincerely yours,

Geraldine A. June for

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

IWADE RESEARCH INSTITUTE OF MYCOLOGY CO.,LTD.

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January 15, 2002

RECEIVED
JAN 24 2002

Dr. Robert Moore
Office of Nutritional Products, Labeling,
and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Dr. Moore:

SUBJECT: Disposition of Iwade 75-day Notification
95S-0316 RPTs 49 & 76

This letter is to inform you that Iwade Research Institute of Mycology, will no longer pursue the premarket notifications for extract of *Agaricus blazei* Murrill.

We have determined that the dried mushroom has been marketed prior to October 15, 1994. Therefore we intend to market the dried mushroom as a dietary supplement, and will no longer pursue the marketing of the extract product. We wanted to assure that the FDA records reflect this information.

Thank you for your time spent on our project.

Sincerely,

Toshimitsu Sumiya

Toshimitsu Sumiya
President
Iwade Research Institute ofMycology Co., Ltd.
1-9, Suehiro-cho, Tsu, Mie 514-0012, Japan